

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 485
SPONSOR(S): Farkas
TIED BILLS:

Specialty Nursing

IDEN./SIM. BILLS: SB 602

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|-------------------------------------|--------|---------|----------------|
| 1) Health Care Regulation Committee | | Hamrick | Mitchell |
| 2) Health & Families Council | | | |
| 3) | | | |
| 4) | | | |
| 5) | | | |

SUMMARY ANALYSIS

HB 485 provides a definition of "clinical nurse specialist" to mean nurses with advanced degrees and expertise in specialized areas of nursing care. It provides for state certification and title protection for Clinical Nurse Specialists (CNS) who are already nationally certified. The bill provides title protection for Certified Registered Nurse Anesthetists (CRNA) and Certified Nurse Midwives (CNM). The provisions in the bill establish that a person can not present themselves as being a clinical specialist, anesthetist, or midwife unless they have the required training and certification to do so. The Department of Health estimates that 2,065 nurses will apply for CNS certification, based on data from comparable states and the National Council of State Boards of Nursing. Currently the only specialized nursing certification that is licensed in Florida is the advanced registered nurse practitioner.

The bill provides for the registration of advanced registered nurse practitioners (ARNPs) to prescribe medicinal drugs and controlled substances. Currently, ARNPs are authorized to prescribe prescription medications, except controlled substances, under the standards of a protocol agreement with a physician. The bill stipulates that the protocol identify the categories of drugs an ARNP may prescribe under the general supervision of a physician. The protocol must be submitted to the Board of Nursing and include a quality assurance procedure. The supervising physician must be available at all times by phone or other electronic means. It provides for continuing education, fees for registration and provides ARNPs the ability to receive a valid mid-level federal Drug Enforcement Administration number. It redefines the term "practitioner" under the "Florida Comprehensive Drug Abuse Prevention and Control Act" to include ARNPs who hold federal controlled substance registry numbers and are registered with the state to prescribe controlled substances.

Fiscal Impact: According to the Department of Health, the revenue from registration of ARNP's to prescribe medicinal and controlled substances for the first year will be approximately \$1,009,125. According to DOH, the long-term fiscal impact will be negative unless renewal fees are increased from the \$25 for the certification of clinical nurse specialists established in the bill.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill enables ARNPs to prescribe controlled and medicinal drugs, which will allow ARNPs to practice within the scope of their profession to provide greater access to health care. The bill will impact the Department of Health's responsibilities of administration and monitoring of protocol agreements.

Promote personal responsibility-The bill requires only nurses who are certified as clinical specialists by a nationally recognized body to be able to hold themselves out as a certified specialist. The bill provides fees such that the beneficiaries of the legislation will pay a large portion of the cost for implementation.

Empower families-The bill may enable advanced registered nurse practitioners (ARNPs) to provide more services to individuals in underserved and under funded clinics.

B. EFFECT OF PROPOSED CHANGES:

Title Protection for Clinical Nurse Specialists, Registered Nurse Anesthetists, and Certified Nurse Midwives

The bill provides a definition of "clinical nurse specialist" to mean nurses with advanced degrees and expertise in specialized areas of nursing care. It provides for state certification and title protection for Clinical Nurse Specialists (CNS) who are already certified nationally. The bill provides title protection for Certified Registered Nurse Anesthetists (CRNA) and Certified Nurse Midwives (CNM). The Department of Health estimates that 2,065 nurses would apply for CNS certification, based on data from comparable states and the National Council of State Boards of Nursing.

The provisions in the bill will establish that a person can not present themselves as being a clinical specialist, anesthetist, or midwife unless they have the required training and certification to do so. Currently the only specialized nursing licensure certification is the ARNP. CNSs are licensed in 23 states, but not in Florida. A CNS is prepared at master's level by several nursing programs in Florida, but since there is no title protection, any nurse can use the CNS title.

Prescribing Authority for Medicinal Drugs and Controlled Substances by Advanced Registered Nurse Practitioners

The bill also provides for registration of Advanced Registered Nurse Practitioners (ARNPs) to prescribe medicinal drugs and to prescribe controlled substances. The provisions for ARNPs will assist their patients in receiving their medication. As the number and use of advanced registered nurse practitioners has increased in primary care, patients are not able to receive prescriptions for all of their drugs from one practitioner, requiring some patients to have second appointments, delays in treatment, and increased expense for consultations. The bill establishes requirements for protocols with the supervising physician, continuing education, and fees for registration. Additional requirements for prescribing controlled substances include possession of a valid mid-level federal Drug Enforcement Administration registration and continuing education. The bill provides for disciplinary sanctions and criminal penalties. It redefines the term "practitioner" under the "Florida Comprehensive Drug Abuse Prevention and Control Act" to include ARNPs who hold federal controlled substance registry numbers and are registered with the state to prescribe controlled substances. According to the Department of Health, the number of ARNPs in Florida is 11,471. The department estimates that 80% will apply for the medicinal drug registration and of those 50% will apply for the controlled substance registration.

The bill requires an ARNP who prescribes medicinal drugs to: register with the Board of Nursing; complete at least 16 hours of continuing education in pharmacology biennially; and submit a copy of

the protocol between the ARNP and the supervising physician prior to their license renewal. The bill requires general supervision by the physician, and requires the nurse to maintain medical records for each prescription. The Board of Nursing is required to review new applications and documents related to continuing education and protocols, and establish a registration process for prescribing medicinal drugs. The bill provides for the board to adopt rules.

Currently, ARNPs may prescribe drugs, but not controlled substances, upon licensure and establishment of a protocol with a physician. ARNPs are not included on the list of practitioners able to prescribe controlled substances under the Florida Comprehensive Drug Abuse Prevention and Control Act. As a result, ARNPs are not authorized by state statute to be able to obtain a federal Drug Enforcement Administration (DEA) number required by pharmacies to fill their patients' prescriptions. Some insurance companies require pharmacies, when submitting claims for prescriptions, to include a DEA number as an identifier for each prescription submitted, regardless of whether or not it is for a controlled substance.

BACKGROUND

Three General Types of Professional Regulation: Licensure, Certification, and Registration

The bill provides for the certification of clinical nurse specialists. There are three primary forms of regulation used to grant individuals the right or privilege to perform certain activities. They are licensure, certification, and registration. Although these terms are often used interchangeably, the literature on professional regulation makes the following distinctions:

- Licensure is the most restrictive mechanism and entails the creation of a monopoly on the regulated activity of a profession through enactment of profession-specific Practice Acts. Licensed practitioners gain an exclusive right to deliver services, and the profession enjoys protection of its title.
- Certification is less restrictive than licensure. It is achieved through the use of title protection acts that give a designated "recognition" to individuals who meet qualifications set by a regulatory agency. Non-certified individuals may still offer services, but they are prohibited from using the term "certified" or the designated title. Certification is also used in the context of licensure, as in the American Medical Association's scheme of specialty boards which certify physicians specializing in different practice areas. In this context, certification denotes that a licensed practitioner has met certain professional standards.
- Registration is the least restrictive regulatory mechanism and is achieved through registration requirement acts. Registration requires an individual to file his or her name and address with a designated agency. Unlike licensure, registration does not require complex or onerous pre-entry screening requirements, nor is a registration regime exclusionary. It does little more than provide a roster of practitioners.

Specialized Nursing Certification and Advanced Registered Nurse Practitioners

Currently the only specialized nursing licensure certification in Florida is the Advanced Registered Nurse. Section 464.012, F.S., provides for certification of Advanced Registered Nurse Practitioners that have met one or more of the following requirements:

- Completed a post basic education program that prepares nurses for advanced or specialized practice;
- Are certified by a specialty board, such as a registered nurse anesthetist or nurse midwife; or
- Have graduated with a master degree in a nursing clinical specialty area.

Who are Clinical Nurse Specialists?

Clinical Nurse Specialists (CNSs) are licensed registered nurses who have graduate preparation (Master's or Doctorate) in nursing as a Clinical Nurse Specialist. According to the National Association of Clinical Nurse Specialists, they are trained to be expert clinicians in a specialized area of nursing

practice. They can provide direct care, expert consultation to nursing staffs, and implement improvements in health care delivery systems. Their specialty may be identified in terms of:

- A Population (e.g. pediatrics, geriatrics, women's health);
- A Setting (e.g. critical care, emergency room);
- A Disease or Medical Subspecialty (e.g. diabetes, oncology);
- A Type of Care (e.g. psychiatric, rehabilitation); or
- A Type of Problem (e.g. pain, wounds, stress).

Authorization of Advanced Registered Nurse Practitioners to Prescribe Medications

Advanced Registered Nurse Practitioners are authorized to prescribe prescription medications, excluding controlled substances, under standards of a protocol agreement with a physician, as provided by s. 464.003(3)(c), F.S., and Rule 64B9-4.010, Florida Administrative Code.

All medications that the supervising physician has agreed for the ARNP to prescribe must be listed in the protocol. The writing of the protocols and approval of the collaborative practice physician gives the ARNP prescriptive privileges. Nurse practitioners have their own prescription pads.

A nurse practitioner can not write prescriptions for controlled substances. Federal law requires that anyone prescribing controlled substances have a DEA license number. All prescriptions for controlled substances must be written and signed by a licensed physician.

A Drug Enforcement Administration (DEA) Number is Required to Prescribe Controlled Substances

Federal regulation, Title 21, section 1306.5, CFR requires prescriptions for controlled substances to indicate the federal registration number, which is the Drug Enforcement Administration (DEA) number that is issued to physicians, veterinarians, dentists, and podiatrists authorized to prescribe controlled substances.

The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illegal production of controlled substances. It places all substances regulated under existing federal law, in one of five schedules based on the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs.

Through the registration of all those authorized by the DEA to handle controlled substances the Controlled Substances Act creates a closed distribution system for controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.

Chapter 893, F.S., sets forth the *Florida Comprehensive Drug Abuse Prevention and Control Act*. It classifies controlled substances into five schedules based on federal law in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

- Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States.
- Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs.
- Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid.

- Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Section 893.04 (1)(c)2., F.S., prohibits pharmacists from filling prescriptions for controlled substances without a DEA number indicated on the prescription.

Advanced Registered Nurse Practitioners and DEA Numbers in Florida and Other States

Because ARNPs cannot prescribe controlled substances by statute or rule, they cannot obtain a DEA number. Nurse Practitioners in Florida cannot receive a DEA number because there is no statutory authority for these practitioners to prescribe controlled substances.

The Drug Enforcement Agency does issue Mid-Level Practitioner DEA numbers to ARNPs in 44 states and the District of Columbia where these practitioners are authorized to prescribe controlled substances.

Supervising Physicians DEA Numbers are used by Pharmacist for Prescriptions Written by Advanced Registered Nurse Practitioners

It has become common procedure for pharmacies to use the federal DEA number as a unique identifier for billing reimbursement from insurance companies and managed care companies.

Because ARNPs can not obtain DEA numbers, Florida pharmacists use the DEA number of the physician who supervises the ARNP to bill insurers and managed care companies for prescriptions written by ARNPs.

By using the DEA number to bill insurers the pharmacist labels the prescription with the name of the physician rather than the name of the ARNP who actually wrote the prescription. This practice is a violation of the rules of the Florida Board of Pharmacy that requires that the name of the actual prescribing practitioner be on each prescription label.

C. SECTION DIRECTORY:

Section 1. Amends s. 464.003, F.S., to define the scope of practice of a clinical nurse specialist and amends the definition of advanced registered nurse practitioner.

Section 2. Creates s. 464.0115, F.S., to establish certification criteria for clinical nurse specialists, fees for application and renewal, and rulemaking authority.

Section 3. Amends s. 464.012, F.S., to include clinical nurse specialists within the specializations of advanced registered nurse practitioners.

Section 4. Creates s. 464.0125, F.S., to establish registration requirements for an advanced registered nurse practitioner who prescribes medicinal drugs and who prescribe controlled substances.

Section 5. Amends s. 464.015, F.S., to provide title protection for "Clinical Nurse Specialist" and the abbreviation "C.N.S."; "Certified Registered Nurse Anesthetist" and the abbreviation "C.R.N.A."; and "Certified Nurse Midwife" and the abbreviation "C.N.M."

Section 6. Amends s. 464.016, F.S., to prohibit a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife to practice without an active license or certification and the use of the title unless the person is duly licensed or certified.

Section 7. Amends s. 893.02, F.S., to include advanced registered nurse practitioners in the list of practitioners authorized to prescribe controlled substances.

Section 8. Reenacts s. 921.0022, F.S., to incorporate changes in s. 464.016, F.S., by reference.

Section 9. Amends s. 458.348, F.S., to correct a cross-reference.

Section 10. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

According to the Department of Health, 2,065 nurses are expected to apply for Clinical Nurse Specialist certification. This is based on data from comparable states and the National Council of State Boards of Nursing. The number of advanced registered nurse practitioners (ARNPs) in Florida is 11,471. It is expected that 80% will apply for the medicinal drug registration and of those 50% will apply for the controlled substances registration.

1. Revenues:

According to the Department of Health, due to the renewal cycle, it is estimated 6,100 will renew their registration in year 1 and 3,100 will renew in year 2 at \$25 each.

| Estimated Revenue | 1 st Year | 2 nd Year | 3 rd Year | 4 th Year |
|-----------------------------------|----------------------|----------------------|----------------------|----------------------|
| CNS Certification | \$51,625 | \$5,000 | \$5,000 | \$5,000 |
| CNS Renewal | \$0 | \$0 | \$7,000 | \$13,650 |
| Registration-Medicinal Drugs | \$690,000 | \$15,000 | \$15,000 | \$15,000 |
| Registration-Controlled Substance | \$115,000 | \$5,000 | \$5,000 | \$5,000 |
| Renewal-Registration | \$152,500 | \$77,500 | \$152,000 | \$77,000 |
| Total Estimated Revenues | \$1,009,125 | \$102,500 | \$184,500 | \$116,150 |

2. Expenditures:

According to the Department of Health, the Division of MQA would require 1 additional FTE for the Clinical Nurse Specialist portion of this bill and 3 additional FTEs for the prescribing portion.

| Estimated Expenditures | 1 st Year | 2 nd Year | 3 rd Year | 4 th Year |
|--|----------------------|----------------------|----------------------|----------------------|
| Salaries | | | | |
| 1- Nurse Consultant, PG 077 (CNS) | \$40,829 | \$54,439 | \$54,439 | \$54,439 |
| 1Nurse Consultants, PG 077(registration) | \$40,829 | \$54,439 | \$54,439 | \$54,439 |
| 1-RSII, PG 17 (registration) | \$28,912 | \$38,550 | \$38,550 | \$38,550 |
| 1-RSI, PG 15 (registration) | \$26,379 | \$35,172 | \$35,172 | \$35,172 |
| Expense | | | | |
| Non-recurring expense for 1 FTE (CNS) | \$3,343 | | | |
| Non-recurring expense for 2FTEs (registration) | \$6,686 | | | |
| Non-recurring expense for 1 FTE (registration) | \$2,791 | | | |
| Recurring expense for 1 Nurse Consultant w/ limited travel (CNS) | \$10,390 | \$10,390 | \$10,390 | \$10,390 |
| Recurring expense for 1 Nurse Consultants with limited travel (registration) | \$10,390 | \$10,390 | \$10,390 | \$10,390 |
| Recurring expense for 1 RSII (reg) | \$6,403 | \$6,403 | \$6,403 | \$6,403 |
| Recurring expense for 1 RSI (reg) | \$5,195 | \$5,195 | \$5,195 | \$5,195 |

| | | | | |
|---|------------------|------------------|------------------|------------------|
| Operating Capital Outlay | | | | |
| Standard OCO pkg for 1 FTE (CNS) | \$1,900 | | | |
| Standard OCO pkg for 2FTEs (registration) | \$3,800 | | | |
| Standard OCO pkg for 1 FTE (registration) | \$2,100 | | | |
| Human Resource Services | | | | |
| 1 FTE for CNS | \$393 | \$393 | \$393 | \$393 |
| 3 FTEs for registration | \$1,179 | \$1,179 | \$1,179 | \$1,179 |
| Total Estimated Expenditures | \$191,519 | \$216,550 | \$216,550 | \$216,550 |

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
None.

2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A broader prescribing authority may enable advanced registered nurse practitioners (ARNPs) to provide more services to individuals in underserved and under funded clinics.

Employers will have to revise job descriptions for Clinical Nurse Specialists to conform to the new certification requirements. Employees that are currently using the title of CNS may need additional education and/or certification to meet requirements or may not qualify to use the title at all.

D. FISCAL COMMENTS:

According to the Department of Health, the bill establishes a new licensing profession (CNS) and two new registrations for existing profession (ARNP). The CNS licensing profession is projected to operate in a deficit unless the application and renewal fee caps are raised above the \$25 established in the bill. The first two year expenditures are projected at \$122,077 with revenues for these two years to be \$56,625.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:
None.

B. RULE-MAKING AUTHORITY:

The bill provides adequate rule-making authority to the Department of Health to implement the provisions of the bill. However, the Department of Health has stated that the effective date of the bill

does not allow sufficient time to the Board of Nursing to engage in rule-making to promulgate rules and develop procedures necessary to implement the provisions provided for in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Board of Nursing reports that as the number of ARNPs has increased in primary care, patients are sometimes required to have second appointments, delays in treatment, and increased expenses for consultations because of the limitations on ARNP prescription writing.

Amendments have been proposed to test the expanding prescribing authority in a pilot project.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES